REMARKS

Claims 1-24, 26-36, and 38-55 are currently pending in this application after entry of the instant response. Claims 25 and 37 were cancelled without prejudice. Claim 47 is withdrawn from consideration. Claims 1-24, 26-36, 38-46 and 48-55 are rejected. Applicants reserve the right to file a continuing application directed to the withdrawn and/or cancelled claims which continuing application is entitled to priority of the present invention.

Reconsideration and withdrawal of the pending rejections is respectfully requested in view of the remarks submitted herein.

Response to Rejections under 35 U.S.C. §102

Claims 22-24, 30-31, 33, and 36 are rejected under 35 U.S.C. §102(b) as being anticipated by Chandler, et al. (*J. Clin. Microbiol.* 31(10):2641-2647, 1993). Applicants respectfully disagree with the Examiner's contention.

The Examiner contends that Chandler's probes may be switched such that the poly (dA)-capture probe described by Chandler may be used as the unlabeled signal sequence probe and Chandler's labeled RNA probe may be used as the capture probe as claimed in the instant invention. However, applicants assert that the two probes may not be exchanged in order to result in the claimed invention.

As an initial matter, Chandler teaches away from using additional probes besides the KOG-500 detector probe and the capture probe described therein (see, pg. 2642, Col. 1, under the section entitled, "Probes"). Although the Examiner has interpreted Chandler as teaching both the use of (1) the KOG-500 detector probe as the equivalent of the instant SSP and the poly(dA) capture probe as the equivalent of the instant CSP, as well as (2) the KOG-500 detector probe as the equivalent of the instant CSP and the poly(dA) capture probe as the

equivalent of the instant SSP, Chandler does not provide teaching or guidance as to how the second of these scenarios would function. Chandler's poly(dA) capture probe is used as a means for separating the target complex from the non-target complex. However, if the poly(dA) capture probe is being used as a detector probe, Chandler does not teach or demonstrate how the target would be detected. In fact, the poly(dA) capture probe may simply hybridize to the poly (dT) sequence attached to paramagnetic beads, without the target. Furthermore, if the poly(dA) capture probe functions as the unlabeled signal sequence probe, Chandler is silent as to how the target sequence would be detected without a labeled probe.

In an embodiment of the instant invention, poly (dT) probes, which are unlabeled, are used in conjunction with additional probes, such as bridge probes, to ensure detection. Chandler does not describe how one skilled in the art would detect the target using an unlabeled poly (dA) probe as a SSP that binds to an oligo (dT) paramagnetic bead. How would a complex of a target, a poly(dA) probe, and an oligo(dT) bead be distinguishable from a complex of just the poly(dA) probe and oligo(dT) bead if the SSP is the poly(dA) unlabeled probe?

Moreover, in the non-radioactive method for detection, Chandler uses an antibody that is specific to digoxigenin (DIG), where the digoxigenin is attached to a nucleic acid probe. Chandler does not teach or suggest the use of an antibody specific for a DNA-RNA hybrid. The instant claim 22 has been amended such that the antibody specifically binds the DNA-RNA hybrid of the hybrid complex. Chandler describes on page 2643, DIG-labeled detector probes and a sheep antibody against DIG conjugated to alkaline phosphatase. Chandler does not teach or suggest the use of an antibody specific for DNA-RNA hybrids. As each and every element of a claim must be disclosed in a cited reference in order to be novelty destroying, applicants assert that Chandler does not teach or suggest the use of an antibody that binds the DNA-RNA hybrid

of the hybrid complex nor how detection without a detectable label would occur as claimed. Therefore, Chandler does not anticipate claim 22 or depending claims 23-24, 30-31, 33 and 36. Reconsideration and withdrawal of this rejection under §102(b) are respectfully requested for the above reasons.

Response to Rejections under 35 U.S.C. §103

Applicants acknowledge the withdrawal of the rejection to claims 1-21, 32, 38-46, and 48-55 under 35 U.S.C. §103(a) as being unpatentable over Collins (USPN: 5,750,338) in view of Murakami, et al. (Nucleic Acids Res., 19(15):4097-4102, 1991) and Shah, et al. (USPN: 5,629,156).

Claims 26-29 and 34-35 stand rejected under 35 U.S.C. §103(a) over Chandler, et al., and in view of Shah, et al. Specifically, as mentioned above, the Examiner contends that Chandler teaches unlabeled SSP, and in combination with Shah, et al., teach a method of detecting a target nucleic acid having a capture sequence probe that is biotinylated and a solid phase that is coated with streptavidin. Applicants respectfully disagree.

Claims 26-29 and 34-35, directly or indirectly depend from claim 22. Independent claim 22 has been amended such that the antibody binds the DNA-RNA hybrid of the hybrid complex. As detailed above, the only feasible method that Chandler reports of is the use of a labeled RNA probe which the Examiner has characterized to be the same as the claimed signal sequence probe. However, the signal sequence probe in the cited claims is unlabeled. Therefore, Chandler does not teach or suggest the claimed method. Specifically, Chandler does not provide guidance as to how the unlabeled poly(dA) probe as SSP and KOG-500 probe as

CSP would function to detect the target, nor describes the use of an antibody specific for DNA-RNA hybrids. Shah has been combined with Chandler for the teaching that the capture probe is labeled with biotin and a solid phase coated with streptavidin. However, regardless of whether Shah teaches these elements, Chandler does not teach or suggest using an unlabeled SSP for the detection of a target nucleic acid sequence and an antibody that specifically binds to a DNA-RNA hybrid. Neither Chandler nor Shah, either alone or in combination, teach or suggest the use of an antibody specific for a DNA-RNA hybrid in the method of detecting a target nucleic acid as recited in claim 22. Therefore, Chandler and Shah do not make obvious depending claims 26-29 and 34-35. It would not have been obvious to one skilled in the art to modify the Chandler method with the biotin labeled capture probe and streptavidin coated solid phase described in Shah to result in the claimed invention which uses unlabeled signal sequence probes and an antibody that specifically binds to DNA-RNA hybrids. Thus, because the limitations of the claims are not taught or suggested by either Collins or Shah, a *prima facie* case of obviousness has not been established. Reconsideration and withdrawal of these §103 rejections are respectfully requested.

Response to Non-Statutory Double Patenting Rejection

Claims 1-24, 26-36, 38-46, and 48-55 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-52 and 54-92 of copending Application No. 10/311,645 (Publn. No. US 2004/0214302). Since the conflicting claims have not in fact been patented, this is a provisional obviousness-type double patenting rejection.

In response, applicants respectfully request that the provisional double-patenting rejection be held in abeyance due to the provisional nature of the rejection until one of the applications is allowed. Upon notice of otherwise allowable subject matter, applicants will address the rejection. Applicants note that it is proper when dealing with otherwise allowable subject matter in co-pending applications to withdraw a provisional rejection in the most advanced application, allow it to issue, and make a (non-provisional) rejection in the remaining application.

Thus, applicants respectfully submit that the claims as presented herein are allowable over the art of record, and respectfully request that the respective rejections and objections be withdrawn.

Dependent Claims

Applicants have not independently addressed all of the rejections of the dependent claims. Applicants submit that for at least similar reasons as to why independent claims 1, 2, 22, 40, and 50 from which all of the dependent claims depend are believed allowable as discussed *supra*, the dependent claims are also allowable. Applicants however, reserve the right to address any individual rejections of the dependent claims and present independent bases for allowance for the dependent claims should such be necessary or appropriate.

Thus, applicants respectfully submit that the invention as recited in the claims as presented herein is allowable over the art of record, and respectfully request that the respective rejections and objections be withdrawn.

CONCLUSION

Based on the foregoing amendments and remarks, applicants respectfully request reconsideration and withdrawal of the rejection of claims and allowance of this application. Applicants respectfully believe that the subject application is patentably distinguished over the art and that the claims are in condition for allowance. An action passing this case to issue is courteously urged.

AUTHORIZATION

The Commissioner is hereby authorized to charge any additional fees which may be required for consideration of this Amendment to Deposit Account No. **13-4500**, Order No. 2629-4017.

In the event that an extension of time is required, or which may be required in addition to that requested in a petition for an extension of time, the Commissioner is requested to grant a petition for that extension of time which is required to make this response timely and is hereby authorized to charge any fee for such an extension of time or credit any overpayment for an extension of time to Deposit Account No. **13-4500**, Order No. 2629-4017.

Respectfully submitted,
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Dated: February 13, 2007 By: _____

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